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PATENT

#7

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Given et al.
Serial No.: 10/068,016 Group Art Unit: 3736
Filed: February 5, 2002
Publication No.: US 2002/0165466 A1
For: **Systems, Methods and Products for Diagnostic Hearing Assessments Distributed Via the Use of a Computer Network**

Date: December 27, 2002

Commissioner for Patents
Washington, DC 20231

REQUEST FOR REPUBLICATION

Sir:

Pursuant to CFR §1.221(b), Applicants request the republication of the above-referenced patent application because the United States Patent and Trademark Office ("the Office") has made a material mistake, which is apparent from Office records. This request is timely filed within two months of the date of publication (which was November 7, 2002).

(1) More particularly, Applicants submit that Table 2 printed at page 7 of the publication has a line with data that is shifted from Table 2 provided in the filed application. The data in the table in the line labeled "All subharmonics" (copy attached) was shifted to the right one column when published. Please correct the published table to the original format as shown below.

Table 2: Maximum permissible harmonic distortion, expressed in percent *

	Air Conduction				Bone Conduction		
Frequency (Hz)	125	250	500 - 4000	6000 - 16000	250	500 - 750	1000 - 5000
Hearing level	75	90	110	90	20	50	60
Second harmonic	2	2	2	2	5	5	5
Third harmonic	2	2	2		2	2	2
Fourth & each higher harmonic	.3	.3	.3		2	2	2
All subharmonics		.3	.3	.3			
Total harmonic	2.5	2.5	2.5	2.5	5.5	5.5	5.5

(2) Applicant also requests that published Claim 56 on page 16 of the published application be corrected to remove the word "it" from the beginning of line 5 of this claim.

user for at least about 20ms and such that it is equal to or less than about 50ms. For bone-conducted signals, the rise or onset time shall be no less than 20ms. When the tone is terminated, the "fall" time is less than about 20 ms. The duration of the tonal plateau can be presented to the patient such that it is equal to or above about 150 ms.

As shown above in **Table 1**, the testing protocol can include 10 different frequencies ranging from 125Hz to 12000Hz. Additional or lesser frequencies can be used, depending on the applicable test standard, although typically, the test frequencies will be between 20-20,000 Hz. The frequency accuracy for each test signal tone generated can be presented to the patient such that the signal is within about 1% of the indicated tone frequency.

In certain embodiments, the hearing assessment presentation signals can include frequency tones, narrow band noise, broadband noise, recorded noise and speech, as well as live speech. In certain embodiments, the device **50, 50'** may also be configured such that the harmonic distortion of the tone frequencies, are able to meet the current ANSI standards, an example of a current standard ANSI-S3.6 1996 is listed in **Table 2**. Thus, in certain embodiments, the maximum level of the harmonics of the test tone relative to the level of the fundamental may be presented so as to not exceed the values given in **Table 2** below.

Table 2: Maximum permissible harmonic distortion, expressed in percent *

Frequency (Hz)	Air Conduction 125	250	500 - 4000	6000 - 16000	Bone Conduction 250	500 - 750	1000 - 5000
Hearing level	75	90	110	90	20	50	60
Second harmonic	2	2	2	2	5	5	5
Third harmonic	2	2	2		2	2	2
Fourth & each higher harmonic	.3	.3	.3		2	2	2
All subharmonics		.3	.3	.3			
Total harmonic	2.5	2.5	2.5	2.5	5.5	5.5	5.5

* ANSI-S3.6 1996

In operation, the desired hearing tone presentation is output to the output device **60** and to the patient. In response, the patient can indicate a response to the tone to the input device **72**. The input device **72** can be a voice activated or speech recognition input microphone, or a physical input port such as a keypad, button,

[0066] In certain embodiments, the hearing assessment presentation signals can include frequency tones, narrow band noise, broadband noise, recorded noise and speech, as well as live speech. In certain embodiments, the device **50**, **50'** may also be configured such that the harmonic distortion of the tone frequencies, are able to meet the current ANSI standards, an example of a current standard ANSI-S3.6 1996 is listed in Table 2. Thus, in certain embodiments, the maximum level of the harmonics of the test tone relative to the level of the fundamental may be presented so as to not exceed the values given in Table 2 below.

TABLE 2

Maximum permissible harmonic distortion, expressed in percent *

	Air Conduction				Bone Conduction		
Frequency (Hz)	125	250	500–4000	6000–16000	250	500–750	1000–5000
Hearing level	75	90	110	90	20	50	60
Second harmonic	2	2	2	2	5	5	5
Third harmonic	2	2	2		2	2	2
Fourth & each higher harmonic	.3	.3	.3		2	2	2
All sub-harmonic	.3	.3	.3				
Total harmonic	2.5	2.5	2.5	2.5	5.5	5.5	5.5

* ANSI-S3.6 1996

[0067] In operation, the desired hearing tone presentation is output to the output device **60** and to the patient. In response, the patient can indicate a response to the tone to the input device **72**. The input device **72** can be a voice activated or speech recognition input microphone, or a physical input port such as a keypad, button, screen-contact software switch, or physical switch. In certain embodiments, the input device can be (or include) a video camera **85** which is video linked to the test administration site **10** so that the clinician can visually monitor the patient's response during the test. Further, two individually operable input devices can be employed, one for use when the patient acknowledges a tone to the right ear and one for when the patient acknowledges hearing from the left ear. It will be appreciated that, in some embodiments, the input device may be on the output transducer **60** headset itself as an alternative to the housing body of the device **50**.

[0068] As is also shown in **FIG. 3**, the device **50** may, in some embodiments, include a microphone **80** to measure the ambient or environmental noise within the testing room or locale, at the patient site **20**. This embodiment can allow the system to assure that the test complies with appropriate standards, such as ANSI S3.1-1999. This standard specifies the maximum permissible noise levels (MPANL) allowed in a room for audiometric threshold assessment. In certain embodiments, the microphone **80** can be configured to measure or detect sound pressure levels or noise in the range of between about 20 Hz to 20 kHz, and may, in some embodiments, detect sound pressure levels at octave intervals 125 to 8,000 Hz or up to 12,000 or greater Hz. The microphone **80** may operate prior to initiation of the testing procedure to determine what the noise or sound level is and if a particular type of output device **55** should be employed (such as whether supra-aural or insert earphones are appropriate to meet the applicable standard).

[0069] Sound Level Measurement of Ambient Noise

TABLE 3

Octave band ears covered maximum permissible ambient noise levels

Octave Band Intervals (Hz)	Supra-aural Earphones	Insert Earphones
125	39.0	67.0
250	25.0	53.0
500	21.0	50.0
1000	26.0	47.0
2000	34.0	49.0
4000	37.0	50.0
8000	37.0	56.0

Values are in dB re: 20 uPa to nearest 0.5 dB

[0070] In certain embodiments, the microphone **80** may be operable substantially continuously during the entire testing procedure to assess the noise during the test and to note either or both at the test administration site **10** or the local site **20** the detection of an undesirable ambient sound level or when or if a particular step or sequence should be repeated because of a detection of noise above a certain threshold level. The local system **20***s* may also include an audio analyzer **82** operably associated with the microphone **80** and the processor **70**. The audio analyzer **82** can receive sound input from the microphone **80** and analyze whether the ambient noise level is suitable. The device **50** may include a visual indicator (**90**, **FIG. 5**) to note when the sound level is acceptable, unacceptable, or when it is approaching an impermissible level. A general threshold can be used for all types of devices, or can be monitored for the type of output device **60** used during a particular test. Examples of visual indicators (typically positioned at one or both of the local end **20** or test administration **10** sites) include multiple color light emitting diodes (LEDs) such as green and red LED's (and may include blue or yellow as well), or text or design/icon active matrix screen displays which visually affirm or identify the level and the like. The test administration site **10** can receive (upload) data regarding the ambient sound level before and/or during the test for evaluation during the procedure.

[0071] In other embodiments, a passive biotelemetry reading of the structure/operation of the ear (i.e., middle ear analysis, cochlea hair cell response, and the like) can be obtained. This measurement or reading can be administered in addition to (or separately from) the tone hearing test protocol. The biotelemetry sensor can be incorporated into the transducer output device **60** or can be an additional component. In operation, an operator at the test administration site can activate the local biotelemetry sensor in the ear of the subject and the associated measurement can be passively obtained (without requiring the subject to verbally or visually communicate). The measurement can be relayed to the test administration site **10** via the communication link to the computer network **15**. As will be discussed below, the processor **70***p* associated with the patient site **20** can relay the information during the test by generating a webpage **70***c* and relaying that to a client at the test administration site.

[0072] The biotelemetry methods/systems can acquire multiple data sets and transmit them through the computer

55. A method for performing a hearing evaluation test over a computer network, comprising the steps of:

obtaining at least one of a tympanometric measurement of middle ear pressure and compliance or the measurement of evoked otoacoustic emissions of a patient using a computer network;

transmitting commands from a test administration site to a local patient testing site during at least a portion of said obtaining step;

generating the hearing assessment signals at the local patient site in response to said transmitting step; and

relaying data between the local site to a clinician located at the test administration site during at least a portion of said obtaining step so that the clinician can evaluate the patient's response to the hearing assessment signals, the test administration site being remote from the local site.

56. A method of controlling a electrophysiological auditory evaluation test using one or more of otoacoustic emissions and tympanometry, the method comprising the steps of:

serving web pages from a web server associated with an otoacoustic auditory evaluation test device configured to measure otoacoustic emissions including at least one of middle ear compliance and cochlear hair cell responses, to a web client which indicates a status of the otoacoustic evaluation test;

receiving requests from the web client which provide parameters for performing the otoacoustic evaluation test; and

controlling at least a portion of the operation of the test based on the parameters of the received request from the web client.

57. A hearing evaluation device, comprising:

a web server;

a diagnostic test device operably associated with the web server and configured so as to be controlled by the web server; and

wherein the web server is further configured to host socket connections to a web client that provide data that indicates a status of a diagnostic hearing test, receive requests from the web client that provides parameters for performing the diagnostic

diagnostic test device based on the parameters of the received request from the web client.

47. A hearing evaluation device for generating hearing assessment signals at a local patient site, comprising:

a processor configured to communicate over a computer network;

a tone generator operably associated with the processor, wherein, in operation, said tone generator is configured to generate tones at a plurality of selected frequencies in the frequency range of between about 20-20,000 Hz;

an output device operably associated with the tone generator, wherein, in operation, said output device adapted to deliver the tones of the hearing assessment signals to a patient undergoing a hearing evaluation; and

an input device operably associated with the processor, said input device configured to indicate a patient's response to each of the tones of the hearing assessment signals;

wherein the hearing evaluation device is configured to receive commands from a remote site through said processor computer network to select or adjust the tones generated by the tone generator.

48. A hearing evaluation device according to claim 47, further comprising:

a microphone configured to detect ambient noise; and

an audio analyzer in electrical communication with the microphone for measuring the sound level detected by the microphone.

49. A device according to claim 48, wherein the device is configured to operate independently of a local computer.

50. A method of controlling a hearing test, the method comprising the steps of:

serving web pages from a web server associated with a hearing test device to a web client which indicate a status of the hearing test;

receiving requests from the web client which provide parameters for performing the hearing test; and

controlling operation of the hearing test device based on the parameters of the received request from the web client so as to provide control of the hearing test.

51. A method according to claim 50, wherein the hearing test comprises obtaining a biotelemetry measurement of the ear of the subject for evaluating at least one of middle ear pressure and compliance characteristics or transient and/or distortion product emission levels in the ear.

52. A method according to claim 50, wherein the hearing test comprises a diagnostic hearing test of selected tones.

53. A method according to claim 52, wherein the requests from the web client are common gateway interface (CGI) requests which specify parameters for performing the diagnostic hearing test.

54. A method according to claim 50, further comprising the step of automatically periodically requesting web pages from the server so as to periodically update the status of the hearing test.

55. A method for performing a hearing evaluation test over a computer network, comprising the steps of:

obtaining at least one of a tympanometric measurement of middle ear pressure and compliance or the measurement of evoked otoacoustic emissions of a patient using a computer network;

transmitting commands from a test administration site to a local patient testing site during at least a portion of said obtaining step;

generating the hearing assessment signals at the local patient site in response to said transmitting step; and

relaying data between the local site to a clinician located at the test administration site during at least a portion of said obtaining step so that the clinician can evaluate the patient's response to the hearing assessment signals, the test administration site being remote from the local site.

56. A method of controlling a electrophysiological auditory evaluation test using one or more of otoacoustic emissions and tympanometry, the method comprising the steps of:

it serving web pages from a web server associated with an otoacoustic auditory evaluation test device configured to measure otoacoustic emissions including at least one of middle ear compliance and cochlear hair cell responses, to a web client which indicates a status of the otoacoustic evaluation test;

receiving requests from the web client which provide parameters for performing the otoacoustic evaluation test; and

controlling at least a portion of the operation of the test based on the parameters of the received request from the web client.

57. A hearing evaluation device, comprising:

a web server;

a diagnostic test device operably associated with the web server and configured so as to be controlled by the web server; and

wherein the web server is further configured to host socket connections to a web client that provide data that indicates a status of a diagnostic hearing test, receive requests from the web client that provides parameters for performing the diagnostic hearing test, and control operation of the diagnostic test device based on the parameters of the received request from the web client.

58. A method of controlling a diagnostic hearing test, the method comprising the steps of:

hosting a socket connection at a web server for the transfer of data associated with a diagnostic hearing test device to a client which indicates a status of the diagnostic hearing test;

establishing test parameters of the hearing test device over the hosted socket connection;

controlling operation of the diagnostic test device over the hosted socket connection based on the parameters received from the client over the hosted socket connection so as to provide control of the diagnostic hearing test;

receiving results associated with the diagnostic hearing test at the client over the hosted connection; and

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